

## **REMARKS**

### **Status of Claims**

Claims 33-51 are in the case and presented for the Examiner's consideration.

Claims 1-32 are cancelled.

Claims 33-51 are new.

For the reasons that follow, Applicants believe all claims are now in condition for allowance.

### **Amendments to the Claims:**

In order to expedite prosecution of the present application, Applicants have cancelled claims 1-32 without prejudice. Cancellation of said claims does not constitute any admission regarding patentability of the cancelled subject matter. Applicants reserve a right to pursue this subject matter in the present or other application(s).

Support for new independent claim 33 can be found, for example, on page 7, lines 9-10; and pages 10 and 11 of the published application. Claims 34-42 depend from Claim 33 and support for them can likewise be found in the disclosure as stated above.

Support for new independent claim 43 can be found, for example, on page 8, lines 22-24, page 9 lines 1-7; pages 10-11 and claims 14-16 of the published application. Claims 44-51 depend from Claim 43 and support for them can likewise be found in the disclosure as stated above.

No new matter is added.

**Claim Rejections under 35 U.S.C. § 112, second paragraph**

Claims 1-32 were rejected by the Examiner under 35 U.S.C. § 112, second paragraph for reasons set forth on page 2 of the office action dated July 26, 2007 (Office Action). This rejection is rendered moot in light of the cancellation of claims 1-32 and by the introduction of new claims that are believed by the Applicants to be in condition for allowance. Further, the Applicants have used proper Markush language in drafting the new claims with respect to pharmaceutically acceptable salts. For these reasons, the Applicants respectfully request that the Examiner withdraw his rejection under 35 U.S.C. § 112, second paragraph.

**Claim Rejections under 35 U.S.C. § 112, first paragraph**

Claims 30-32 were rejected by the Examiner under 35 U.S.C. § 112, first paragraph for reasons set forth on page 3 of the Office Action. This rejection is rendered moot in light of the cancellation of claims 1-32. However, some of the language of the new claims is directed at the treatment of a group of related cancers and, as to this language, the Applicants respectfully traverse this rejection for reasons as set forth below.

The Examiner rejected now cancelled claims 30-32 as failing to comply with the enablement requirement, suggesting that the claimed subject matter related to treatment of cancer generally. New independent claim 33 is limited to the treatment of a disease or condition caused by a genetic defect in a gene that mediates homologous recombination (HR). Similarly, new independent claim 43 is limited to the induction of apoptosis of cells defective in a gene that mediates HR. Thus, the claims are not directed towards treatment of cancers generally, but defined genetic defects and the treatment of diseases related to this defect. The skilled addressee is taught that a suitable subject for treatment with the specified PARP inhibitors is

one having a defect in a gene that mediates HR. The specification contains numerous examples of genes involved in HR.

The inventors have shown that cells defective in a gene that mediates HR are hypersensitive to PARP inhibitors. This was a surprising and inventive observation, and the scope of the claims is commensurate with the inventors' contribution to the art.

For these reasons independent claim 33 is believed to recite patentable subject matter and allowance is, therefore, respectfully requested. Claims 34-42 depend from claim 33 and are allowable for the same reasons given above for claim 33. Independent claim 43 is likewise believed to recited patentable subject matter and its allowance is respectfully requested. Claims 44-51 depend from Claim 43 and are allowable for the same reasons given above for claims 33 and 43.

#### **Claim Rejections under 35 U.S.C. § 102(b) and (e)**

Claims 1-3 and 25-29 were rejected by the Examiner under 35 U.S.C. ' 102(b) as being anticipated by U.S. Patent 6,495,541 to Webber et al. (Webber et al. '541) and U.S. Patent 6,548,494 to Webber et al. (Webber et al. '494) for reasons set forth on page 4 of the Office Action. Claim 4 was rejected by the Examiner under 35 U.S.C. § 102(e) as being anticipated by U.S. published application number 2004/0248879 to Canan-Koch et al. (Canan-Koch et al.) for reasons set for on page 4 of the Office Action. These rejections are rendered moot in light of the cancellation of claims 1-32. Furthermore, the new claims presented in this response recite limitations not found in any reference cited by the Examiner and are, therefore, not anticipated. Neither are the new claims obvious in light of the cited references. For these reasons (discussed in more detail below) Appellants respectfully traverse any rejection by the Examiner under 35 U.S.C. § 102 or 103.

To anticipate a claim, the reference must teach every element of the claim. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. See, e.g., Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) and MPEP 2131.

With respect to new independent claim 33, the references cited by the examiner stand silent as to the claimed limitation of “selecting the mammal having the genetic defect” wherein the genetic defect is in a gene that mediates homologous recombination. As the above stated limitation is not expressed, implied or inherent in the cited references, rejection of claim 33 under 35 U.S.C. § 102(b) is improper.

With respect to new independent claim 43, the references cited by the examiner stand silent as to the claimed limitation of “selecting the cells having the genetic defect” wherein the genetic defect is in a gene that mediates homologous recombination. As the above stated limitation is not expressed, implied or inherent in the cited references, rejection of claim 43 under 35 U.S.C. § 102(b) is improper.

To establish a prima facie case of obviousness, the Examiner should demonstrate some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference as he has suggested. He should also show that his suggested modification of the prior art was reasonably expected to succeed, and that the prior art reference teaches or suggests all of the claim limitations. See, e.g., In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); KSR Int'l Co. v. Teleflex, Inc. 127 S.Ct. 1727 (2007) (“There is no necessary inconsistency between the idea underlying the TSM test and the Graham analysis”).

The concept underlying the present invention is the surprising and inventive finding that cells deficient in HR are hypersensitive to PARP inhibitors relative to wild type cells (see page 3, lines 18-19). Thus, the use of the PARP inhibitors of Formulas I-III provides for a method of treatment that is both effective and selective in the killing of cancer cells and which can be administered without the need for other treatments such as radiotherapy or chemotherapy. The hypersensitivity to the compounds of Formulas I-III of cells deficient in HR is a surprising effect, which consequently would not be obvious from the cited reference. As such, it is not reasonable to believe that one ordinarily skilled in the art would have made such a modification to the cited reference with the reasonable expectation that doing so would have resulted in the method of treating a disease or condition as recited in claim 33 or inducing apoptosis in affected cells as recited in claim 43. As the references cited by the Examiner do not teach or suggest all of the limitations of claims 33 and 43 it is improper to reject the same under 35 U.S.C. § 103(a) as unpatentably obvious.

For the reasons stated above, the Applicants believe that new independent claims 33 and 43 are in condition for allowance as are the claims that depend from them for the same reasons.

## **Conclusion**

Applicants believe all claims are now in condition for allowance. Should there be any issues that have not been addressed to the Examiner's satisfaction, Applicants invite the Examiner to contact the undersigned attorney.

If any fees other than those submitted herewith are due in connection with this response, including the fee for any required extension of time (for which Applicants hereby petition), please charge such fees to Deposit Account No. 14-1431.

Respectfully submitted,

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